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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,745	12/28/2001	Anne M. Pianca	AB-164U	3645

23845 7590 06/06/2005

ADVANCED BIONICS CORPORATION  
25129 RYE CANYON ROAD  
VALENCIA, CA 91355

EXAMINER
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SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/035,745

Applicant(s)

PIANCA ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 13, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Real (Pat. No. 5,649,936).

Regarding claim 13, Real discloses a lead introduction system comprising a stereotactic frame (see Figs. 7, 10, etc.), a first cannula 20 dimensioned to be larger than a predetermined hole size in the patient's skull to prevent entry into the brain and held in a substantially fixed position by the stereotactic frame, a second cannula 230 slidable within the first cannula and having a proximal end extending beyond the proximal end of the first cannula and a distal end extending beyond the distal end of the first cannula and into the body (see Figs. 5 and 19), wherein the second cannula is dimensioned to permit insertion through a predetermined hole size in the patient's skull, wherein the second cannula is supported by the first cannula and wherein the stimulation lead is insertable through the second cannula.

Lacking any specific definition in the specification of the term *cannula*, the examiner will consider the term to apply to any tube or tube-like structure within which instruments or probes may be inserted.

One could also interpret element 228 to represent a first cannula of a length larger than the diameter of the predetermined hole, since the applicant has not specified which dimension of the cannula is to be larger than the hole size. Furthermore, whether or not the diameter of cannula 228 is dimensioned to be larger than a predetermined hole size in the skull to prevent entry into the brain depends upon the size of the hole – a non-element of the apparatus invention.

Regarding claim 16, Real discloses a method of introducing a brain stimulating lead comprising holding a first cannula 228 (or 20) in a substantially fixed position completely external to the brain (see Fig. 19), slidably supporting a second cannula 230 (or 95) with the first cannula, positioning the second cannula with a proximal end extending beyond the proximal end of the first cannula and a distal end extending beyond the distal end of the first cannula so that the second cannula extends at least partially into the patient's brain (see Figs. 5 and 19), and inserting a brain stimulating lead (mapping electrode 150) through the second cannula (see col. 10, lines 5-38).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Real in view of Sunde (EP 1 062 973 A1).

Real does not discuss the use of macroelectrodes attached to the second cannula. Sunde, however, discloses such an arrangement for neural stimulation (note Figs. 1 and 2) and teaches that this configuration allows one to perform electro-physiological recording and electrode implantation in one step (col. 6, lines 1-6). Given the fact that Real discloses that his apparatus and method may be directed to a variety of different instruments and procedures including brain microstimulation and brain mapping (see col. 11, lines 49-61), and given the obvious advantage of performing a single step to enact electrode placement and recording as taught by Sunde, those of ordinary skill in the art would have considered the limitations expressed within these claims to be a matter of obvious design dependent upon the application at hand and desired procedure.

Art Unit: 3762

**Conclusion**

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lobdill et al. disclose a typical procedure for implanting a deep brain electrode with guide cannula (col. 10, lines 59-67).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

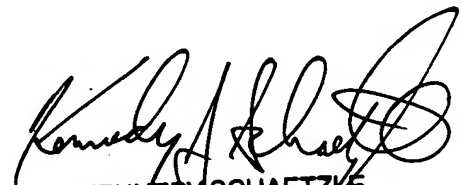
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
May 31, 2005



KENNEDY SCHAETZLE  
PRIMARY EXAMINER